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Latex and Vinyl Nonsterile Examination Gloves: Status Report on Laboratory Evaluation of Defects by Physical and Biological Methods

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We have reported previously (H. R. Kotilainen, J. P. Brinker, J. L. Avato, and N. M. Gantz, Arch. Intern. Med. 149:2749–2753, 1989) that the quality of nonsterile examination gloves available for clinical use may be extremely variable. In view of the concern over human immunodeficiency virus and hepatitis B virus transmission to health care workers, the continuing variability of gloves available for use, and the need for a simple and safe test, we have evaluated 2,500 vinyl (five brands) and 2,000 latex (four brands) gloves by the 300-ml and the newly proposed 1,000-ml water tests and for permeability to herpes simplex virus type 1 and poliovirus type 1, respectively. While all 300-ml watertight gloves were unlikely to leak herpes simplex virus type 1 (1.3% vinyl; 0.5% latex), poliovirus was recovered much more frequently (8.9% vinyl, 6.1% latex). In all gloves that passed the 1,000-ml test, herpes simplex virus type 1 was not recovered. Poliovirus was recovered infrequently (1.4% vinyl, 1.5% latex). Preliminary analyses suggest that the 1,000-ml water test has significantly increased sensitivity over the 300-ml water test in the detection of small holes in both vinyl and latex gloves that may allow the passage of viral particles. Gloves that pass a 1,000-ml water challenge are unlikely to allow the passage of a small virus such as poliovirus. Given that human immunodeficiency virus, hepatitis B virus and herpes simplex virus type 1 are larger particles than poliovirus, gloves that pass the 1,000-ml water test theoretically could provide better protection.

In December 1987, the Infection Control Department at the University of Massachusetts Medical Center became aware of three nurses in the medical intensive care unit (MICU) who had developed herpetic whitlow from herpes simplex virus type 1 (HSV-1) on the right index finger during a 5-week period (5).

During this investigation, one type of vinyl examination glove that was in use in the MICU was not in use in other intensive care units. This finding was not unusual for hospitals because of a nationwide shortage. To have adequate inventory for the facility, gloves may have been bought from five or six suppliers at a time. During this time, numerous reports had been received from the MICU of gloves that had ripped or torn during manually intensive procedures or had obvious defects when taken from boxes. Several reports of blood or other body fluids observed on the inside of what appeared to be otherwise intact gloves after prolonged patient contact were also noted. We had difficulty believing that MICU personnel were more likely to damage gloves during use than trauma unit personnel. Several patients in the trauma unit with oral herpes and with copious secretions had recently been cared for and yet no health care worker assigned to that area developed whitlow. When endonuclease mapping of the HSV-1 isolates of the patients and employees demonstrated that all employee isolates were similar to one patient isolate, concerns were raised that inferior gloves may have been responsible.

To determine whether available examination gloves would be permeable to HSV-1 in use, a glove finger pipette assay was devised. When HSV-1 was recovered in 2.5 to 10% of the gloves in a pilot survey, a larger investigation was undertaken.

We have reported previously that vinyl gloves (seven brands) failed the 300-ml water test 4 to 28% of the time while latex gloves (seven brands) failed 0 to 6% of the time (5). The brand that had been in use in the MICU had a 28% failure rate. Watertight vinyl gloves passed HSV-1 0 to 2.6% of the time, while watertight latex gloves did not leak the virus. In a companion study, it was observed that, if a glove had a defect detected by the 300-ml water test, HSV-1 could be recovered in the glove finger pipette assay 100% of the time.

These data were disturbing to us for several reasons. While overall vinyl glove integrity was significantly less than latex glove integrity, some brands or lot numbers of vinyl gloves were better than latex gloves. Some experts believe that intact vinyl is as protective as intact latex, but the more important and immediate need was to provide intact gloves of any material to our employees.

Given that HSV-1 is a larger particle than other potential human viral pathogens such as hepatitis B virus, we wondered whether other viral agents smaller than HSV-1 would pass through a leaky glove. Should other occupational infections be anticipated even when gloves were worn?

Although infection is the result of a combination of many factors, including dose and virulence of the agent, mode of transmission, portal of entry, and host defenses, increased disease had already been seen. Health care professionals such as critical-care nurses have continual prolonged exposure to blood and body fluids. Many of these persons in our facility have chapped, cut, abraded hands.

Testing gloves for permeability to each virus of concern is not a practical approach. What is needed is a surrogate test

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that uses nonhazardous materials applicable to a large-volume manufacturing situation that imparts reasonable confidence that biological agents will not pass. To investigate these possibilities, latex and vinyl gloves were evaluated by the 300-ml and the newly proposed 1,000-ml water tightness tests. Gloves that are watertight in both 300-ml and 1,000-ml tests should be tested with HSV-1 and with a smaller viral particle. If watertight gloves could be shown to be nearly impenetrable to small viral particles such as poliovirus, then we could be reassured that larger viruses of great concern such as hepatitis B virus and human immunodeficiency virus would be unlikely to pass.

MATERIALS AND METHODS

Gloves. Some 2,000 latex and 2,500 vinyl nonsterile examination gloves from four and five manufacturers, respectively, were obtained for testing. Gloves were selected from unopened boxes as they were received by the materials handling department. Only one lot of each brand was available. Only gloves free of visually apparent defects were tested.

Viruses and tissue culture. HSV-1 and poliovirus type 1 (PV-1) were obtained from stock cultures in the Clinical Virology Laboratory which had originally been obtained from patient isolates. Determination of viral titer was performed by the Reed-Muench method (6). Minimal essential media with Earle salts and fetal calf serum were obtained from GIBCO Laboratories, Grand Island, N.Y. MRC-5 cells were obtained from Viromed Laboratories, Inc., Minneapolis, Minn.

Water tightness tests. Gloves were tested by the military standard method with 300 ml of water (7). Position and number of leaks were noted. All gloves that leaked were then tested by the 1,000-ml water test to determine whether additional leaks were present. To perform the 1,000-ml test, each glove was attached to a glass cylinder by a foam padded hose clamp. One liter of room temperature distilled water was added to the glove through the cylinder. Water testing is illustrated in Fig. 1. Each glove was hung for 5 min, and the number and position of leaks were noted. Gloves that did not leak when challenged with 300 ml of water were divided into three groups for additional testing. These tests included the 1,000-ml water tightness test and permeability to HSV-1 and PV-1. Gloves that passed the 1,000-ml water test were also tested for permeability to HSV-1 and PV-1. The testing scheme is illustrated in Fig. 2.

Virus permeability tests. The index finger of a watertight glove was removed and attached to a 10-ml serological pipette with a rubber band. This assembly was placed inside a 50-ml serum bottle and immersed in 10 ml of minimal essential medium with 2% fetal calf serum. The glove pipette assembly was injected with 2 ml of either 10^6 50% tissue culture infective doses of HSV-1 or 10^5 tissue culture infective doses of PV-1 per ml, incubated at 22°C with agitation for 1 h. A 0.1-ml aliquot was removed from the serum bottle and placed on MRC-5 cells. Twenty aliquots were tested from each sample. One hour was allowed for viral adsorption. Cultures were incubated at 36°C and observed daily for cytopathic effect for 5 days. Positive controls consisted of removing five aliquots from the inside of the glove finger pipette assembly and assaying as above on MRC-5 cells. In addition, viability tests of stock virus with and without exposure to vinyl or latex gloves were conducted. No brand of glove was shown to have any toxic effect on either HSV-1 or PV-1. All viability controls were positive.

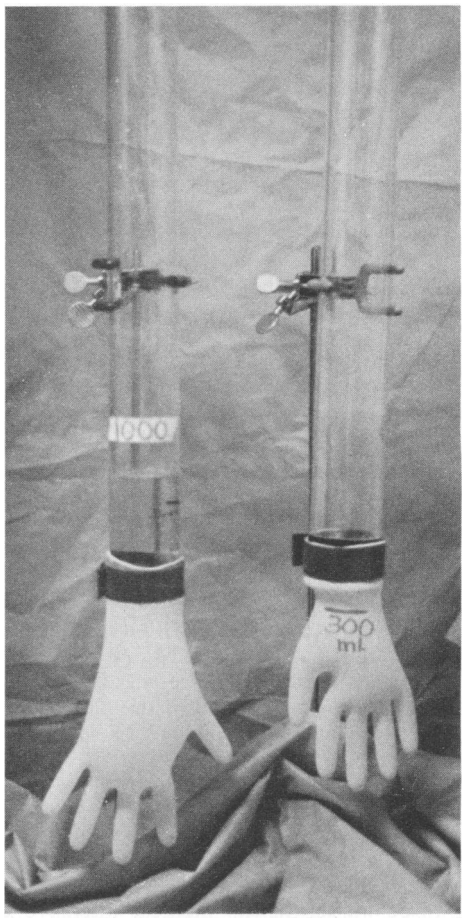

FIG. 1. Apparatus for performing the 300- and 1,000-ml water challenge tests. A glass cylinder was added to the 300-ml test glove for visual comparison.

RESULTS

The results with five brands of vinyl or plastic gloves and four brands of latex gloves after evaluation by the 300- and 1,000-ml water tightness tests are listed in Tables 1 and 2. Statistically significant variability in failure rates from the 300-ml to the 1,000-ml test was seen among all manufactur-

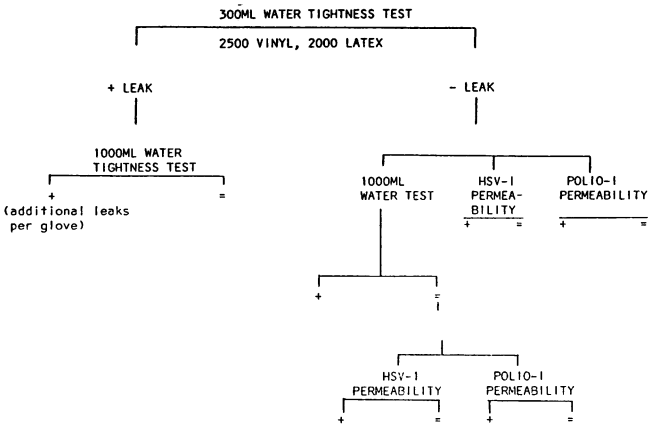

FIG. 2. Testing scheme.

TABLE 1. Results with 2,500 vinyl/plastic nonsterile examination gloves in 300- and 1,000-ml water tightness tests

Manufacturer	300-ml test		1,000-ml test	
	No. tested	No. (%) of failures	No. tested	No. (%) of failures
A	500	44 (8.8)	152	32 (21.1)
B	500	62 (12.4)	146	47 (32.2)
C	500	16 (3.2)	161	17 (10.5)
D	500	14 (22.8)	128	60 (46.8)
E	500	14 (2.8)	163	18 (11.0)

ers with the exception of vinyl gloves obtained from manufacturers C and E (paired t test; $P < 0.5$). In the 300-ml water test, vinyl glove failure rates ranged from 2.8 to 22.8%, with an average of 10%, while latex glove failures ranged from 0.4 to 15.2%, with an average of 6.4%. In the 1,000-ml test, failure rates for vinyl ranged from 10.5 to 46.8%, with an average of 23.2%. Latex glove failures in the 1,000-ml test ranged from 3.0 to 19.2%, with an average of 15.5%. While a tendency was observed toward higher failure rates for each brand in the 1,000-ml water test if initially higher failure rates were seen in the 300-ml water test, this association did not apply in every situation. Vinyl glove B with a failure rate of 12.4% had 39% more failures detected by the 1,000-ml test. On the other hand, vinyl glove A with 8.8% failures initially had 42% more failures in the 1,000-ml test.

When gloves that had failed the 300-ml water test were rechallenged with 1,000 ml of water, new additional leaks were found for every brand. These data are presented in Table 3. Both vinyl and latex gloves had additional defects when tested with 1,000 ml of water. Brands of vinyl gloves that had higher failure rates in the 300-ml test initially had a greater number of additional leaks detected with the exception of manufacturer E. These differences were found to be statistically significant (paired t test; $P < 0.01$). The same trend was not seen for latex gloves. The brand of latex gloves from source F had only 2 of 500 gloves failing the 300-ml test. These two gloves had multiple new leaks when tested with 1,000 ml of water. Brand G with 6.4% failures had 56.3% more leaks detected, while brand H with 15.2% 300-ml failures had only 43.4% additional leaks detected. For both latex and vinyl, up to five new defects per glove were noted.

The 300-ml watertight vinyl gloves, when exposed to HSV-1, were positive from 0.6 to 2.3%, with an average failure rate of 1.3%. Comparably tested latex gloves leaked HSV-1 0 to 0.6%, with a 0.5% average failure rate (Table 4). However, when poliovirus permeability was assayed, 3.1 to 14.1% more virus for vinyl and 2.8 to 7.8% more virus for latex were recovered (Table 5).

Some 287 vinyl gloves (60, 49, 72, 34, and 72 tested from manufacturers A, B, C, D, and E, respectively) and 263 latex gloves (80, 63, 47, and 73 tested from manufacturers F, G, H, and I, respectively) that passed the 1,000-ml test were assayed for permeability to HSV-1. No virus was recovered. When a companion sample of 288 vinyl and 263 latex 1,000-ml watertight gloves was tested for PV-1 permeability, 0 to 0.3% of the vinyl gloves were positive (average, 4 of 288, 1.4%), while 0 to 2.5% of the latex gloves were positive (4 of 263, 1.5%) (Table 6). Differences with respect to glove material, virus used, or manufacturer were not statistically significant. When permeability to HSV-1 was used as the standard, the sensitivity of the 1,000-ml water test was not greatly increased. However, when PV-1 permeability was assumed to be the standard, the 1,000-ml water test was much more sensitive than the 300-ml water tightness test (Table 7).

TABLE 2. Results with 2,000 latex nonsterile examination gloves in 300- and 1,000-ml water tightness tests

Manufacturer	300-ml test		1,000-ml test	
	No. tested	No. (%) of failures	No. tested	No. (%) of failures
F	500	2 (0.4)	166	5 (3.0)
G	500	32 (6.4)	156	30 (19.2)
H	500	76 (15.2)	141	48 (34.0)
I	500	18 (3.6)	161	14 (8.7)

TABLE 3. Results with latex and vinyl/plastic gloves that failed 300-ml water tightness test when rechallenged in 1000-ml water tightness test

Manufacturer	No. tested	No. (%) of gloves with new leaks	Leaks detected	
			Mode/glove	Range/glove
Vinyl/plastic				
A	44	18 (41)	1	1–4
B	62	34 (55)	2	1–3
C	16	4 (25)	1	1–3
D	114	73 (64)	2	1–6
E	14	8 (57)	2	1–5
Latex				
F	2	2 (100)	2	
G	32	18 (56.3)	2	1–4
H	76	33 (43.4)	3	1–5
I	18	6 (33.3)	2	1–3

DISCUSSION

In spite of the concern that has been expressed by researchers (1) and the media (2) over the variable quality of nonsterile examination gloves available for use, we have seen little improvement since our evaluations began over a year ago. Average failure rates for vinyl were comparable for both studies, with gloves leaking water after 300 ml of water 10% and 11.1% of the time. However, average latex glove failures were much higher in these experiments than before (1.4 versus 6.4%), with one brand failing 76 of 500 times (15.2%).

TABLE 4. Results with 300-ml watertight gloves (vinyl and latex) in HSV-1 permeability assay

Manufacturer	No. tested	No. that failed	%
Vinyl/plastic			
A	152	2	1.3
B	146	3	2.1
C	161	1	0.6
D	128	3	2.3
E	163	1	0.6
Latex			
F	166	1	0.6
G	156	1	0.6
H	141	0	
I	161	1	0.6

TABLE 5. Results with 300-ml watertight gloves (vinyl and latex) in PV-1 permeability test

Manufacturer	No. tested	No. that failed	%
Vinyl/plastic			
A	152	13	8.6
B	146	19	13.0
C	161	8	5.0
D	128	21	16.4
E	163	6	3.7
Latex			
F	166	14	8.4
G	156	12	7.8
H	141	4	2.8
I	161	8	5.0

The way in which defects can be expected to appear during a manufacturing process and the sampling process used to select gloves for testing may be important considerations. As we would see several defective gloves in a row, we are assuming that machine-produced defects are probably nonrandom. Current industry standards call for selecting every 20th or 50th glove for testing with a total sample of 50 to 100 gloves. Such a scheme is likely to underestimate the number of faulty gloves in a lot, especially since a lot may exceed several thousand gloves (3). Development of a proper, yet reasonable sampling strategy is clearly an area for additional research.

Rates of penetration of HSV-1 in 300-ml watertight vinyl gloves were comparable to our previous experience in which 0 to 2.6% versus 0.6 to 2.3% of the gloves failed. Previous to this, we have been unable to pass HSV-1 through a 300-ml watertight latex glove. The method we describe here increased the amount of virus used from 10^5 to 10^6 50% tissue culture infective doses per ml and may account for our positive findings.

We found a significant number of both latex and vinyl gloves without leaks which, after being test with 300 ml of water, were permeable to poliovirus. The 300-ml water test is believed to be able to find holes as small as 10 μm. If size were the only consideration and given that HSV-1 is 120 to 150 nm, it should freely pass through holes potentially undetectable by the 300-ml test. Our data do not support this finding and suggest that factors other than size are important in designing effective barrier materials. The much higher recovery rates of poliovirus in 300-ml watertight gloves when compared with the data for HSV-1 may be explained by not only the size of the particles but also the structure and composition. Unlike HSV-1, poliovirus, approximately 20 nm in diameter, does not have a lipid envelope. We are unaware of any data that specifically address the relationship between viral lipid and glove interaction. Yet, since the presence of lipid in virus is associated with a high degree of susceptibility to germicides and small size and absence of lipid are associated with resistance to lipophilic germicides (such as mercurials and some phenolic or quaternary ammonium compounds) (4), these relationships with respect to gloves should be investigated.

TABLE 6. Results with 288 vinyl/plastic and 263 latex 1,000-ml watertight nonsterile examination gloves in poliovirus permeability test

Manufacturer	No. tested	No. that failed	%
Vinyl/plastic			
A	60	2	3.3
B	49	0	
C	72	1	1.4
D	34	1	2.9
E	73	1	1.4
Latex			
F	80	2	2.5
G	63	0	
H	47	1	2.3
I	73	1	1.4

TABLE 7. Sensitivity of 300- and 1,000-ml water tightness tests in prediction of HSV-1 and PV-1 permeability

Test	% Sensitivity	
	HSV-1	PV-1
300-ml vinyl	96.2	78.9
300-ml latex	97.7	77.1
1,000-ml vinyl	100	97.7
1,000-ml latex	100	96.0

Our results suggest that the 1,000-ml water tightness test provides increased sensitivity for the detection of leaks. Significantly different increases in the discovery of additional leaks were seen commonly. Given our data for HSV-1 permeability in 300-ml watertight gloves, we were not surprised when no virus was recovered from the gloves tested with 1,000 ml of water. However, in view of the large percent reduction of PV-1 failures in the 1,000-ml tested group compared with the 300-ml group, the proposed test may lead to better-quality gloves.

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